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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,388	06/11/2007	Fredrik Nicklasson	PCH0918USPCT	8119
27777	7590	09/20/2010	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			WELTER, RACHAEL E	
			ART UNIT	PAPER NUMBER
			1611	
			NOTIFICATION DATE	DELIVERY MODE
			09/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/591,388	Applicant(s) NICKLASSON ET AL.	
	Examiner RACHAEL E. WELTER	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/4/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

In a phone call on 9/9/10, the examiner asked applicant's attorney, Mr. Federman, to elect a specific form of nicotine from those recited in instant claim 19. Applicant elected nicotine free base with traverse. However, after further consideration and a prior art search, the examiner is withdrawing this species requirement. All the claims pending will be examined on the merits.

Claim Status

Claims 16-26 are pending. Claims 1-15 are cancelled. Claims 16-26 are newly added claims.

Foreign Priority

Acknowledgement is made of applicant's foreign priority claim to Sweden 0400685-4 filed 3/19/04. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 4, 2006 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statement was considered by the examiner. A signed copy of form 1449 is enclosed herewith.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites "...wherein said device is occlusive." However, such a limitation is unclear because the device is comprised of both a patch and a means for iontophoretic delivery. It is not clear what is occlusive on the device. Does applicant mean the entire device is occlusive or does applicant just mean the backing material of the patch is occlusive? Applicant's clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-18 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (US Patent No. 5,415,629; Published 5/16/1995).

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Henley teaches an apparatus for programmable iontophoretic or iontophoretic-ultrasonic transdermal delivery of medication across the skin or other biological membrane (abstract). Henley teaches that a passive transdermal delivery patch can be combined with a programmable, wearable ionosonic or iontophoretic drug delivery apparatus to improve medical management of pain, drug/substance detoxification, and many other illnesses (column 5, lines 58-64). The apparatus can be used to deliver nicotine among other drugs (column 5, lines 31-35). The device comprises a medicament carrying layer and an electrically conductive means electrically connected to the medicament carrying layer (claim 1). There is a programmable means in the device for controlling the depth of penetration of medicament into the skin. In a preferred embodiment of the invention, the device is in the form of a band wherein the inner surface may be an adhesive, an open cell material, peptide-impregnated material, or other similar matrix (column 6, lines 14-18).

Although Henley suggests the use of nicotine in its devices, it is not immediately envisaged and therefore the instant rejection is made under obviousness.

It would have been obvious to an artisan of ordinary skill at the time the invention was made to look at the guidance provided by Henley and incorporate nicotine in the device. One would have been motivated to do so since Henley suggests the use of nicotine as a suitable alternative among medicaments administered. Furthermore, it is within the skill of an artisan to select a given medicament depending on the desired treatment and the particular needs of a patient population.

Regarding the limitation, where first administration (transdermal patch) is detachable from the second iontophoretic administration, the examiner directs applicant to Figure 1 of Henley. The oscillator driver and iontophoretic driver (iontophoretic part) are separate from the electrode (transdermal part) and are attached via wires. Therefore, one would reasonably assume that the two administration parts would be detachable and that the device could be unwired and deconstructed.

Regarding the limitation where the device is occlusive, it is the examiner's position that Henley's transdermal delivery devices would exhibit such properties. It is noted that the instant invention has a thin aluminum layer in its device acting as a barrier to nicotine diffusion through the backing material of its device (see instant specification pg. 14, lines 24-26). Henley also teaches a metallic foil on its electrode which comprises a flexible sheet forming a conductive matrix (column 7, lines 53-59). As such, it would be reasonable to assume that Henley's transdermal delivery devices would exhibit occlusive properties just like the instant invention.

Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (US Patent No. 5,415,629; Published 5/16/1995) as applied to claims 16-18 and 25 above and in further view of Hansson (US 2004/0191322; Published 9/30/04).

The disclosure of Henley is discussed above.

Although Henley teaches that its devices can deliver nicotine, Henley does not explicitly teach that its devices deliver nicotine free bases, nicotine salts, nicotine inclusion complexes, or nicotine cation exchangers wherein nicotine is with polyacrylate.

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Hansson teaches nicotine-containing compositions that can be administered by any convenient route including buccal, nasal, ocular, pulmonary, topical, or transdermal routes (paragraph 0050). The nicotine can be administered in the form of bases or salts wherein salts include nicotine tartrate and nicotine hydrochloride (paragraph 0046). Additionally, Hansson teaches that nicotine can be incorporated as cation exchange resin complexes with groups consisting of methacrylic containing carboxylic functional groups and inclusion complexes with cyclodextrin (paragraph 0004). According to Hansson, different salts, complexes, and combinations of nicotine bases/salts are used to achieve different release rates (paragraphs 0047-0048).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to incorporate different combinations as well as different forms of nicotine in each delivery aspect of Henley's delivery devices. One would have been motivated to do so since Hansson teaches that such nicotine forms are conventionally used in transdermal devices. Furthermore, one would have been motivated to do so depending on the desired release rate or the needs of a particular patient population.

Conclusion

Claims 16-26 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643